RCT on the Management of Early Pregnancy Failure
SERIOUS ADVERSE EVENT REPORT FORM

Site	Patient No.	Letter Code	Visit	Sequence
		0 0		

A. DESCRIPTION OF ADVERSE EVENT

1. Date of onset: ___ ___ ___ - ___ ___ - 2 0 0 ___ (Month / Day / Year) — FM09DT

2. Event description

		Yes	No	
A.	Hemorrhage resulting in blood transfusion	(1)	(2)	AE_HEMOR
B.	Uterine perforation requiring surgical procedure	(1)	(2)	AE_SURG
C.	Hospital admission	(1)	(2)	AE_HOSP
D.	Death	(1)	(2)	AE_DEATH

Date of Death: ___ ___ ___ - ___ ___ - ___ ___ ___ ___ (mmm / dd / yyyy) — DEATHDT

3. Describe event: _____ — AE_SP

4. Relationship to treatment:

Unrelated, due to concurrent illness	(1)		AERELTRT
Unrelated, due to concurrent drug	(2)	Specify _____	AERELRSP
Other known cause	(3)	Specify _____	
Remote	(4)		
Possible	(5)		
Probable	(6)		
Definite	(7)		

IF EVENT IN ITEM 2D "DEATH" IS YES, SKIP TO SECTION B.

5. Date resolved: ___ ___ ___ - ___ ___ - 2 0 0 ___ (Month / Day / Year) — AERSLVDT — Ongoing (1) AEONGO

		Yes	No	
6.	Life threatening	(1)	(2)	LIFETHRT

7.	Outcome	Resolved	(1)	AEOUTCOM
		Persistent at the end of study	(2)	

B. ADMINISTRATIVE MATTERS

SEND A DETAILED DESCRIPTION OF THE SERIOUS ADVERSE EVENT TO THE COORDINATING CENTER.

1. Comments: _____ — GEN_CMNT

2. Person completing form _____ — CERT_SIG — Staff Number: __ __ __ - __ __ __ — CERT_NO

3. Date form completed: ___ ___ ___ - ___ ___ - 2 0 0 ___ (Month / Day / Year) — COMPL_DT